

Application No.:

10/079,931

Applicants:

Kuijpers, et al.

Filed:

February 19, 2002

Title:

TREATMENT OF OCULAR DISORDERS

TC/A.U.:

1644

Examiner:

Nolan, Patrick

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294-70 CON

Dated:

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

I, ROBERTUS WILHELMUS KUIJPERS, declare and say:

- I am one of the inventors of the above-identified U.S. Patent Application, filed 1. on March 6, 2000, which is a continuation-in-part application of U.S.S.N.: 09/258,240, filed February 26, 1999. I am a ophthalmologist practicing in the Netherlands.
- The instant invention was conceived in the Netherlands prior to the filing date 2. of reference at issue, US Patent No: 6,028,099 ("the '099 patent"). In particular, the instant invention was conceived at least as early as October 16, 1996; whereas, the '099 patent was filed on March 13, 1998.
- 3. Attached as Exhibit A is a copy of a case history I began to prepare on October 16, 1996. This history demonstrates that I treated a patient suffering from an ocular disorder associated with choroidal neovascularization with a somatostatin analogue on October 16, 1996. The case history is in Dutch.

- 4. Attached as Exhibit B is an English translation of Exhibit A. As can be seen at the 2nd page in the upper right half, it is indicated that a somatostatin analogue, *i.e.*, octreotide, was used to treat the patient with an ocular disorder associated choroidal neovascularization.
- 5. Subsequent to October 16, 1996, the invention was not abandoned, suppressed nor concealed. The invention was continuously tested, and reduced to practice.
- 6. Attached as Exhibit C is an article by my colleagues and myself (Hagen et al., "Somatostatin and somatostatin receptors in retinal diseases" European Journal of Endocrinology 143: S43-S51 (2000)). This article shows a two-year follow-up of a group of 13 patients with ocular disorders associated choroidal neovascularization treated with a somatostatin analogue. See page 48, Table 2. One of these patients is the one documented in Exhibit A.
- 7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that those statements were made with the knowledge that willfully false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willfully false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: April 12 2005

Robertus Wilhelmus Kuijpers, MD

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